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PATENT
PHA 24,614

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

APPLICANT : Gust H. Bardy *et al.*

SERIAL NO. : 09/441.936 EXAMINER : Kristen L. Droesch

FILED : November 17, 1999 ART UNIT : 3762

FOR : EXTERNAL ATRIAL DEFIBRILLATOR AND METHOD FOR PERSONAL TERMINATION OF ATRIAL FIBRILLATION

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Steven Cha, Reg. No. 44,069
(Name of Registered Rep.)

7/3/02
(Signature and Date)

SUBMISSION OF APPEAL BRIEF

ASSISTANT COMMISSIONER FOR PATENTS
BOX APPEAL
WASHINGTON, D.C. 20231

Sir:

Applicant hereby submits in triplicate copies of the Appeal Brief for the above referenced application, for which a Notice of Appeal was filed on April 3, 2002.

As Applicant qualifies as a large entity, enclosed is a check in the amount of $320.00.

Please charge any additional fees or credit any overpayment to the undersigned firm's Deposit Account No. 14-1270.

Respectfully submitted,

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#10
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7/24/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application

Inventors	:	Gust H. Bardy et al.
Application No.	:	09/441,936
Filed	:	November 17, 2002
For	:	EXTERNAL ATRIAL DEFIBRILLATOR AND METHOD FOR PERSONAL TERMINATION OF ATRIAL FIBRILLATION

APPEAL BRIEF

On Appeal from Group Art Unit 3762

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TABLE OF CASES

I. REAL PARTY IN INTEREST

The real party in interest is the assignee of the present application, Koninklike Philips Electronics. Eindhoven, Netherlands.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-23 have been presented for examination and are currently pending. Claims 7-9 and 16 are allowed, and claim 21 has been indicated to recite allowable subject matter. Claims 1-6, 10-15, 17-20, 22 and 23 stand finally rejected, and form the subject matter of the present appeal.

IV. STATUS OF AMENDMENTS

There are no outstanding Amendments in response to the Final Rejection mailed January 3, 2002.

V. SUMMARY OF THE INVENTION

As shown in Fig. 3. instant claim 1 recites an atrial defibrillator includes a portable. non-implantable housing 20, a pair of defibrillator pads 26, 28, a shock generator and analyzer unit 24. The analyzer unit receives a cardiac signal from the patient, and enables the shock generator if the analyzer unit determines that the patient is experiencing atrial fibrillation. After enablement of the shock generator, an operator

can shock the patient. Rather than provide an automatic shock, the patient is able to be forewarned of a shock, or can refuse such treatment. The device can be operated by laypersons, (including the patient), allowing for a significant cost reduction.

Base claim 3 further includes a safety device 32 to prevent the patient from shocking himself/herself. Base claim 4 includes a verification device to ensure that the unauthorized persons are prevented from operating the shocking generator. Base claim 11 further includes that the analyzer unit is able to determine whether an episode of atrial fibrillation (AF) has been terminated after the operator has applied a shock to the patient by measuring the lengths of R-R intervals (Figs. 2 and 3), calculating respective differences between the lengths, and comparing the calculated differences to a difference threshold value to determine whether the episode of AF has stopped. Claims 13-15, 17-20, and 22-23 recite various methods for determining and treating atrial fibrillation.

VI. ISSUES

1. Whether Claims 20 and 22 stand correctly rejected under 35 U.S.C.§102(b) as allegedly anticipated by Alt et al. (U.S. 5,792,205).

2. Whether Claims 1-2, 10, 12-13, and 18-20 stand correctly rejected under 35 U.S.C.§103(a) as allegedly being obvious by Adams et al. (U.S. 5,207,219 hereafter "Adams'219") in view of Morgan et al. (U.S. 4,610,254 hereafter "Morgan").

3. Whether Claim 3 stands correctly rejected under 35 U.S.C.§103(a) as allegedly being obvious over Adams'219 in view of Brandell (U.S. 6.068,651).

4. Whether Claim 4 stands correctly rejected under 35 U.S.C.§103(a) as allegedly being obvious over Adams'219 in view of Skelton (U.S. 6,292,692).

5. Whether claims 5 and 14 stand correctly rejected under 35 U.S.C.§103(a) as allegedly being obvious over Adams'219 and Morgan, as applied to claims 1 and 13 above and further in view of Ferrari (U.S. 5,824,033).

6. Whether Claims 6, 11 and 15 stand correctly rejected under 35 U.S.C.§103(a) as allegedly being obvious over Adams'219 in view of Morgan and further in view of Brayshaw (U.S. 3,996,569).

7. Whether Claim 17 stands correctly rejected under 35 U.S.C.§103(a) as allegedly being obvious over Adams et al. (U.S. 5,509,925 hereafter "Adams'925") in view of Adamis'219.

8. Whether Claim 23 stands rejected under 35 U.S.C.§103(a) as allegedly being obvious over Adams'219.

VII. GROUPING OF CLAIMS

Claims 1,2 and 10, drawn to a first embodiment of an external atrial defibrillator, stand or fall together. Claim 3 which includes a safety device to prevent a patient from shocking oneself, has a separate basis for patentability and stands alone. Claims 4-5, which include a verification device to prevent unauthorized use, stand or fall together. Claim 6, which includes that the analyzer a certain measurement of R-R signals, stands or falls alone as this claim has a separate basis for patentability. Claim 11, which includes a certain analysis of the R-R signals to determine whether AF is being experienced, has a separate basis for patentability and stands alone. Claim 12, which includes that the analyzer shocks a patient at particular point of an R signal, has a separate basis for patentability and stands alone. Claims 13 and 14, directed to a method, stand or fall together. Claim 15, which includes a specific way that atrial fibrillation is determined by measuring R-R signals, has a separate basis for patentability and stands alone. Claims 17 and 18, which include shocking the patient and making a determination as to whether the patient continues to experience determine atrial fibrillation, stand or fall together. Claim 19 has a separate basis for patentability as this method recites providing a shock at a certain portion of an R-R signal, and thus stands alone. Claims 20 and 22 stand or fall together, and claim 23, which includes providing a shock with a multi-phase waveform , stands alone.

VIII. ARGUMENT

(1) With regard to the rejection of claims 20 and 22 under 35 U.S.C.§102(b) in view of Alt. Applicants respectfully submit that the assertion at page 2, paragraph number 2 of the Final Rejection is incorrect in alleging that Alt discloses the enablement of the shock generator if the operator is authorized. The cited passage of Alt, column 4, lines 8-64, fails in all respects to disclose any of the recited elements. The cited passage. *inter alia*, states that the patient may intiate storage and transmission of ECG information if he/she taps on the device at the implant cite in some predetermined sequence. This teaching fails to disclose or suggest the enablement of a shock generator after determinign that atrial fibrillation is being experienced and the operator is authorized to use the device, and shocking the patient. In any event, Alt discloses that a shock can only be temporarily deferred (column 3, lines 30-32). In contrast , the invention recited by instant claims 20 and 22 does not cause an automatic shock, as this is performed by an operator. As explained by the Applicants in the Background of the Invention, there can be reasons why a patient would not want an automatic shock, and a temporary postponent is not the same as the instant claims recitation of an operator intervening to perform a shock therapy.

For at least the above reason, it is respectfully submitted that claims 20 and 22 are not anticipated by Alt because this reference fails to disclose all of the elements recited by these particular claims.

In addition. the Court of Appeals for the Federal Circuit held in *Verdegaal Bros. v. Union Oil Co. of California*. 814 F.2d 628.631, 2 USPQ2d 1051. 1053 (Fed. Cir. 1987):

> A claim is anticipated only if each and every element as set forth in the claim is found.

either expressly or inherently described,
in a single prior art reference.

As for the reasons previously indicated, the Office Action fails to set forth each and every claimed element in a single reference. It is thus respectfully requested that the Honorable Board overturn this ground of rejection.

(2) With regard to the rejection of Claims 1-2, 10, 12-13, and 18-20 under 35 U.S.C.§103(a) over the combination of Adams'219 in view of Morgan, it is respectfully submitted that:

(i) Claims 1-2 are patentable over the combination of references as Adams discloses an internal automatic defibrillator device, and is completely silent with regard to an operator performing the shock after a shock generator has been enabled in response to an analyzer unit determining that atrial fibrillation has occurred. Applicants also respectfully submit that claims 1 and 2 would not have been obvious over the combination of Adams and Morgan, as the internal automatic shocking generation disclosed by Adams is not a "functional equivalent" of an external system coupled with the inclusion of a shock button as disclosed by Morgan. Furthermore, Morgan discloses a device for treatment of *ventricular fibrillation*, which is a different type of cardiac malfunction than atrial fibrillation, and the treatments are very different.

(ii) In addition, it is respectfully submitted that claim 10 recites that the device determines whether the atrial defibrillation has terminated after a shock has been applied, which is not disclosed or suggested by the combination of Adams'219 and Morgan.

Accordingly, it is respectfully submitted that claims 1, 2 and 10 would not have been obvious to a person of ordinary skill in the art in view of the combination of references.

(iii) With regard to claim 12, Applicants respectfully disagree with the statement in the Final Rejection on page 4, third full paragraph that Adams shows the electrocardiogram shows an R wave having a rising edge and that the analyzer is operable to enable the shock generator during the rising edge of the R wave (Col. 8, lines 10-22). Applicants respectfully submit that Col. 8, lines 10-22 of Adams'219 is void of any such disclosure, teaching, suggestion, or motivation, and that the teaching comes from Applicants' instant claims, not from the combination of Adams'219 and Morgan.

(iv) With regard to claim 13, Applicant respectfully submits that the combination of Adams'219 and Morgan fails to disclose, suggest, or motivate an artisan to provide an method for determining and treating atrial fibrillation as recited.

(v) With regard to claim 18-20, it is respectfully submitted that each of these claims would not have been obvious to a person of ordinary skill in the art over the combination of Adams'219 and Morgan. It is respectfully submitted that the combination of references fails to provide the disclosure, suggestion, or provide motivation to the artisan such that these claims would have been obvious at the time of invention. For example, instant claim 19 recites shocking the patient during a rising edge of an R wave of a patient. For reasons previously indicated, this teaching is void from either reference, or from a purported combination of their teachings. As for instant claim 20, the combination of references fails to disclose or suggest all of the

recited steps. Applicants continue to submit that the teachings of Adams'219 and Morgan are not combinable as their purpose and design are entirely different.

Applicants note that it was held by the Court of Appeals in *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ 2d 1780, 1783-84 (Fed. Cir. 1992) that:

> Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so. Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

In the present case, it is respectfully submitted that the teachings of the combination of references do not overcome the standard of establishing obviousness as exemplified in *Fritch.* Accordingly, it is respectfully requested that this Honorable Board reverse the rejections under 35 U.S.C. §103(a).

(3) Applicants respectfully submit that instant Claim 3 is non-obvious over the combination of Adams'219 and Brandell. Adams'219 discloses an internal automatic system for shocking a patient, where there is no initiation of a patient to have an operator shock a patent after an analyzer unit determines that atrial fibrillation has been experienced. Brandell, in combination with Adams' 219, fails to disclose or suggest an external, non-implantable atrial defibrillator having the feature of a safety device. Accordingly, it is respectfully submitted that this Honorable Board reverse the rejection under 35 U.S.C.§103(a).

(4) Applicants respectfully submit that the combination of Adams'219 and Skelton fails to disclose, suggest, or motivate an artisan such that claim 4 would have been obvious over the combination of references. Adams'219 discloses an automatic

implantable device and Skelton teaches a passcode for a manual device. Applicants submit that providing an external defibrillator for Adams'219 is not a functional equivalent of an internal defibrillator with automatic operation, particularly when it is suggested in the Final Rejection that the "functional equivalent" is then modified to work in a manner inconsistent with the teaching of the reference. It is respectfully submitted that there is no motivation to combine the teachings of Adams'219 and Skelton, and the teaching that allegedly is suggested by the combination of references is actually coming from the Applicant's claims, not from any alleged teachings of the combination of references.

It is respectfully requested that this Honorable Board reverse this ground of rejection under 35 U.S.C.§103(a).

(5) With regard to the rejection of claim 5. it is respectfully submitted that this claim is allowable at least for its dependence from Claim 4, which is believed to be allowable. The addition of Ferrari to the reported combination of Adams'219 and Morgan still fails to disclose, suggest, or provide the motivation that would have made the instant claim obvious to an artisan at the time of invention. It is also respectfully submitted that instant claim 14 is allowable at least for its dependence from claim 13, which is believed to be allowable.

Accordingly, it is respectfully requested that this Honorable Board reverse this ground of rejection under 35 U.S.C.§103(a).

(6) With regard to the rejection of claims 6, 11 and 15 under 35 §U.S.C.§103(a) over the combination of Adams'219 in view of Morgan and Brayshaw. it is respectfully submitted that the combination of references fails to

disclose the recitation in claim 6 of the function of the claimed analyzer with regard to the R-R intervals. In addition, the combination of references fails to disclose or suggest all of the basic elements recited in claim 6. Furthermore, it is respectfully submitted that the teachings of the automatic internal atrial defibrillator disclosed by Adams'219 is not combinable with the external ventricular defibrillator disclosed by Morgan, as the purported modification of Adams'219 would be contrary to the purpose and structure of Adams'219, and against the teachings of that reference. The addition of Brayshaw to the combination still fails to provide the necessary disclosure, suggestion, or motivation that would have made claim 6 obvious to an artisan at the time of invention.

Claims 11 and 15 are also non-obvious to an artisan over the combination of references, as the combination fails to provide the disclosure, suggestion, or motivation that would have made these claims obvious to an artisan at the time of invention, particularly with regard to the instantly claimed teachings regarding the R-R signals.

Accordingly, it is respectfully submitted that this Honorable Board reverse this ground of rejection.

(7) With regard to the rejection of Claim 17 over Adams'925 in view of Adams'219, it is respectfully submitted that the combination of references fails to disclose that a patient is not in atrial fibrillation if the heart rate is outside of a predetermined range. The disclosure in Adams'925 at column 2 is that there is a probability of atrial defibrillation, which is distinguishable from a diagnosis of atrial fibrillation. Probability disclosed by Adams'925 is not the same thing as presently recited by instant Claim 17.

Accordingly, it is respectfully submitted that this Honorable Board reverse this ground of rejection under 35 U.S.C.§103(a).

(8) With regard to the rejection of Claim 23 under 35 U.S.C.§103(a) over Adams'219, it is respectfully submitted that Adams'219 fails to disclose or suggest that an operator shock a patient with a multi-phasic waveform. Firs of all, Adams'219 discloses an internal defibrillator with an automatic shock generation. It would not have been a functional equivalent or mere substitution of Adams'219 to provide same as an external defibrillator with a multi-phasic waveform. Adams'219 is completely silent with regard to a multi-phasic waveform, and it is incorrect for the Examiner to assert that such a waveform is suggested by Adams'219 because Applicants did not assert the criticality of such a waveform. Applicants respectfully challenge any notion that the waveform applied is a matter of design choice, particularly with the seriousness of the application, and the fact the application of a waveform to correct atrial fibrillation has been known in a number of instances to induce the far more lethal ventricular fibrillation, in which a patient loses consciousness and normally dies if not administered help within five minutes. Accordingly, the type of waveform administered to a cardiac patient does matter, and in this particular claim, Applicants recited a multi-phasic waveform, that is not disclosed or suggest by Adams'219.

Accordingly, it is respectfully requested that this Honorable Board reverse this ground of rejection under 35 U.S.C.§103(a).

IX. CONCLUSION

Based on the law and the facts, it is respectfully submitted that none of the appealed claims are anticipated or obvious in view of the applied references. Accordingly, it is respectfully requested that this Honorable Board reverse all grounds of rejection stated in the Final Rejection.

Respectfully submitted,

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X. APPENDIX: THE CLAIMS ON APPEAL

1. (Amended) An atrial defibrillator, comprising:

a portable, non-implantable housing;

a pair of defibrillator pads operable to be applied to the outside of a patient's body;

a shock generator disposed in the housing, coupled to the pads, and operable to shock the patient via the pads in response to a shock command from an operator; and;

an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation.

2. (Amended) The atrial defibrillator of claim 1, further comprising a control device disposed in the housing, coupled to the shock generator and operable to receive the shock command from the operator and to activate the shock generator in response to the shock command.

3. (Amended) An atrial defibrillator, comprising:

a portable, non-implanting housing;

a pair of defibrillator pads operable to be applied to the outside of a patient's body;

a shock generator disposed in housing, coupled to the pads, and operable to shock the patient via the pads;

an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation; and

a safety device disposed in the housing and operable to prevent the patient from activating the shock generator.

4. (Amended) An atrial defibrillator comprising:

a portable, non-implanting housing;

a pair of defibrillator pads operable to be applied to the outside of a patient's body;

a shock generator disposed in the housing, coupled to the pads, and operable to shock the patient via the pads;

an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation; and

a verification device disposed in the housing and operable to prevent an unauthorized person from activating the shock generator.

5. The atrial defibrillator of claim 1 wherein the analyzer is operable to receive the cardiac signal via the pads.

6. (Amended) An atrial defibrillator, comprising:

a portable, non-implantable housing;

a pair of defibrillator pads operable to be applied to the outside of a patient's body;

a shock generator disposed in the housing, coupled to the pads, and operable to shock the patient via the pads;

an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation;

wherein the cardiac signal comprises an electrocardiogram having R-R intervals; and

the analyzer is operable to determine whether the patient is experiencing atrial fibrillation by;

measuring the durations of the R-R intervals,

calculating the respective differences between the lengths of contiguous ones of the R-R intervals,

comparing the calculated differences to a difference threshold, and

determining that the patient is experiencing atrial fibrillation if one of the calculated differences exceeds the threshold.

10. The atrial defibrillator of claim 1 wherein the analyzer is further operable to determine from the cardiac signal whether the atrial fibrillation terminates after the shock generator shocks the patient.

11. (Amended) An atrial defibrillator, comprising:

a portable, non-implantable housing;

a pair of defibrillator pads operable to be applied to the outside of a patient's body;

a shock generator disposed in the housing, coupled to the pads, and operable to shock the patient via the pads;

an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation;

wherein the cardiac signal comprises an electrocardiogram having R-R intervals; and

wherein the analyzer is further operable to determine from the cardiac signal whether the atrial fibrillation terminates after the shock generator shocks the patient by;

measuring the lengths of the R-R intervals,

calculating respective differences between the lengths of continuous ones of the R-R intervals,

comparing the calculated differences to a difference threshold, and

determining that the atrial fibrillation is terminated if one of the calculated differences is less than the difference threshold.

12. The atrial defibrillator of claim 1 wherein:

the cardiac signal comprises an electrocardiogram that includes an R wave having a rising edge; and

the analyzer is operable to enable the shock generator during the rising edge of the R wave and to disable the shock generator outside of the rising edge.

13. (Amended) A method, comprising:

receiving a cardiac signal from a patient;

determining from the signal whether the patient is experiencing atrial fibrillation;

receiving a shock command from an operator; and

shocking the patient with a portable shock generator in response to the shock command if the patient is experiencing atrial fibrillation.

14. The method of claim 13, further comprising:

applying defibrillator pads to the patient;

wherein the receiving comprises receiving the cardiac signal via the pads, and

wherein the shocking comprises shocking the patient via the pads.

15. The method of claim 13 wherein the determining comprises:

measuring the lengths of R-R intervals in the signal;

calculating the respective differences between the lengths of contiguous ones of the R-R intervals;

comparing the calculated differences to a difference threshold; and

determining that the patient is not in atrial fibrillation if one of the calculated differences is less than the difference threshold.

17. (Amended) A method, comprising:

receiving a cardiac signal from a patient;

determining from the signal whether the patient is experiencing atrial fibrillation;

shocking the patient with a portable shock generator if the patient is experiencing atrial fibrillation; and

wherein the determining comprises,

determining the patient's heart rate and

determining that the patient is not in atrial fibrillation if the heart rate is outside of a predetermined range.

18. The method of claim 13, further comprising determining from the cardiac signal whether the atrial fibrillation terminates after shocking the patient.

19. The method of claim 13 wherein the shocking comprises shocking the patient during a rising edge of an R wave in the cardiac signal.

20. A method, comprising:

receiving a cardiac signal from a patient;

determining from the signal whether the patient is experiencing atrial fibrillation;

identifying an operator of a shock generator;

enabling the shock generator if the operator is authorized to operate the shock generator; and

shocking the patient with the shock generator in response to a shock command from the operator if the patient is experiencing atrial fibrillation.

21. The method of claim 20, further comprising disabling the shock generator if the operator is identified as the patient.

22. The method of claim 20 wherein the patient is the operator.

23. An atrial defibrillator, comprising:

a portable, non-implantable housing;

a pair of defibrillator pads operable to be applied to the outside of a patient's body;

a shock generator disposed in the housing, coupled to the pads, and operable to shock the patient via the pads with a multi-phasic waveform; and

an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation.